PATENT APPLICATION

FEB 2 3 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q68142

Tatsuki SHIOTA, et al.

Appln. No.: 10/031,698

Group Art Unit: 1617

Confirmation No.: 8252

Examiner: WANG, Shengjun

Filed: January 23, 2002

For: CYCLIC AMINE CCR3 ANTAGONIST

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant encloses herewith a copy of a Communication

Q68142

INFORMATION DISCLOSURE STATEMENT

U.S. Appln. No.: 10/031,698

from a foreign patent office in a counterpart application citing such documents, together with

an English-language version (if not already included) of at least that portion of the

Communication indicating the degree of relevance found by the foreign patent office.

The submission of the listed documents is not intended as an admission that any such

document constitutes prior art against the claims of the present application. Applicant does

not waive any right to take any action that would be appropriate to antedate or otherwise

remove any listed document as a competent reference against the claims of the present

application.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

Registration No. 30,951

SUGHRUE MION, PLLC

Telephone: (202) 293-7060

Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: February 23, 2005

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SUGHRUE MION, PLLC

Telephone: (202) 293-7060

Facsimile: (202) 293-7860

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| Substitute for Form 1449 | A & DOTO | | | Complete if Known | | |
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| Substitute for Form 1449 | A & D/F IU | | | Application Number | 10/031,698 | |
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| | | | | First Named Inventor | Tatsuki SHIOTA | |
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| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|--------------|--------------|-----------------------------------|------------------|--|--|--|
| Examiner Initials* | Cito | Document N | umber | Publication Date | | | |
| | Cite No.1 | Number | Kind Code ² (if known) | MM-DD-YYYY | Name of Patentee or Applicant of Cited Documer | | |
| | | US 6,410,566 | | 6/2002 | Shiota et al. | | |
| | | US 6,362,177 | | 3/2002 | Shiota et al. | | |
| | | US 4,443,461 | | 4/17/1984 | Ward | | |
| | | US | | | | | |
| | | US | | | | | |
| | | US | | | | | |
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| Examiner Initials* | Cite | FOREIGN PAT | | | Publication Date | Name of Patentee or | |
|-----------------------|------|------------------------------|---------------------|-----------------------------------|------------------|-----------------------------|--------------------------|
| | No.1 | Country Code ³ | Number ⁴ | Kind Code ⁵ (if known) | MM-DD-YYYY | Applicant of Cited Document | Translation ⁶ |
| | | WO | 00/69815 | Α | 11/23/2000 | M. Furuya, et al. | |
| | | CN | 1279668 | Α | 01/10/2001 | N. ENDO, et al. | Abstract |
| | · | wo | 97/24325 | | 7/1997 | | Abstract |
| | | WO | 98/04554 | | 2/1998 | | Abstract |
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| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--------------|--|--------------------------|--|--|
| Examiner Initials* | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published. | Translation ⁶ | | |
| | | KRISHNA VADDI, "CHEMOKINE FACTS BOOK, ACAD. PRESS," 1997 San Diego, CA, pp. 1-2, 10-37, 86-130, 135-137, 142-143, 158-164. | | | |
| | | FRANKLIN H. EPSTEIN, M.D, Luster, D. Andrew, "Chemokines - Chemotactic Cytokines that Mediate Inflammation", The New England Journal of Medicine (February 12, 1998), Vol. 338 pp. 436-445 | | | |
| • | | MARCO BAGGIOLINI "Chemokines and leukocyte traffic" NATURE Vol. 392 pp. 565-568 April 9, 1998 | | | |
| | | JOSEPH HESSELGESSER "Identification and Characterization of Small Molecule Functional Antagonists of the CCR1 Chemokine Receptor" The Journal of Biological Chemistry Vol. 273, No. 25, June 19, 1998 pp. 15687-15692 | | | |
| | | European Communication 11/29/2002 | | | |

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| Substitute for Form 1449 A & B/PTO | Сотр | Complete if Known | | |
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| PE INFORMATION DISCLOSURE | Confirmation Number | 8252 | | |
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| | First Named Inventor | Tatsuki SHIOTA | | |
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| | Examiner Name | WANG, Shengjun | | |
| a inade sine 2 of 3 | Attorney Docket Number | Q68142 | | |

| | U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|--------------------------|--------------|---|--------------------------------|---|--|--|
| <u> </u> | | Document Nur | nber | | | | |
| Examiner Initials* | Cite No. ¹ | Number | Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | | |
| | | US | | | | | |
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| | | US | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|------------------------------|--|--|---|--|---|--|
| Cite | Cite Foreign Patent Document | | Publication Date | Name of Patentee or | | | |
| No.1 | Country Code ³ | Number ⁴ | Kind Code ⁵ (if known) | MM-DD-YYYY | Applicant of Cited Document | Translation ⁶ | |
| | wo | 97/44329 | | 11/1997 | | Abstract | |
| | wo | 98/06703 | | 2/1998 | | Abstract | |
| | wo | 98/30218 | | 7/16/1998 | Smithkline Beecham Corporation | Abstract | |
| | WO | 98/25604 | | 6/1998 | | Abstract | |
| | WO | 98/25605 | | 6/1998 | | Abstract | |
| | wo | 98/25617 | | 6/1998 | | Abstract | |
| | wo | 98/27815 | | 7/1998 | | Abstract | |
| | wo | 98/31364 | | 7/1998 | | Abstract | |
| | wo | 98/38167 | | 9/1998 | | Abstract | |
| | WO | 98/02151 | | 1/1998 | | Abstract | |
| | | <u> </u> | <u> </u> | | | | |
| | Cite No.1 | WO W | Cite No.1 Foreign Patent Document Country Code3 Number4 WO 97/44329 WO 98/06703 WO 98/30218 WO 98/25604 WO 98/25605 WO 98/25617 WO 98/27815 WO 98/331364 WO 98/38167 | Cite No.1 Foreign Patent Document Country Code3 Number4 Kind Code5 (if known) WO 97/44329 WO WO 98/06703 WO WO 98/30218 WO WO 98/25604 WO WO 98/25605 WO WO 98/27815 WO WO 98/31364 WO WO 98/38167 WO | Cite No.1 Foreign Patent Document Publication Date MM-DD-YYYY Country Code3 Number4 Kind Code5 (if known) WO 97/44329 11/1997 WO 98/06703 2/1998 WO 98/30218 7/16/1998 WO 98/25604 6/1998 WO 98/25605 6/1998 WO 98/25617 6/1998 WO 98/27815 7/1998 WO 98/31364 7/1998 WO 98/38167 9/1998 | Cite No.¹ Foreign Patent Document Publication Date MM-DD-YYYY Name of Patentee or Applicant of Cited Document WO 97/44329 11/1997 WO 98/06703 2/1998 WO 98/30218 7/16/1998 Smithkline Beecham Corporation WO 98/25604 6/1998 WO 98/25605 6/1998 WO 98/25617 6/1998 WO 98/27815 7/1998 WO 98/31364 7/1998 WO 98/38167 9/1998 | |

| | NON PATENT LITERATURE DOCUMENTS | | | | | |
|-----------------------|---------------------------------|--|--------------------------|--|--|--|
| Examiner Initials* | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published. | Translation ⁶ | | | |
| | | BRIGHT, COLIN, et al. "Identification of a Non-Peptidic Rantes Antagonist, Vol. 1, No. 1, Bioorganic & Medicinal Chemistry Letters, 1998 pp. 771-774 | | | | |
| | | WARD, G. STEPHEN, et al "Chemokines: understanding their role in T-lymphocyte biology", Biochem. J. (1998) 333, pages 457-470 | | | | |
| | | European Communication 9/17/2003 | | | | |

| Examiner Signature | Date Considered | |
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|------------------------------------|------------------------|------------------|
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| | U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|-----------------------|------------|-----------------------------------|------------------|---|--|--|--|
| ъ . | Cite | Document 1 | Number | Publication Date | | | | |
| Examiner Initials* | No.1 | Number | Kind Code ² (if known) | MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | | |
|--------------------------|--------------|------------------------------|---------------------|-----------------------------------|------------------|--------------------------------|--------------------------|--|--|
| Examiner Initials* | Cite No.1 | Foreign Patent Document | | | Publication Date | Name of Patentee or | | | |
| | | Country Code ³ | Number ⁴ | Kind Code ⁵ (if known) | MM-DD-YYYY | Applicant of Cited Document | Translation ⁶ | | |
| | | EP | 903349 | | | | | | |
| | | wo | 00/9377 | | | | | | |
| | | wo | 00/31033 | | | | | | |
| | | wo | 00/35449 | | | | | | |
| | * | WO | 00/35451 | | | | | | |
| | | EP | 1 201 239 | A1 | 5/2/2002 | Teijin Limited | | | |
| | | wo | 99/01127 | | 1/14/1999 | Smithkline Beecham Corporation | | | |
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| | | European Communication 9/17/2003 | | | | |
| | | RAPPORT, CAROL A., et al., "Molecular Cloning and Functional Characterization of a Novel Human CC Chemokine Receptor (CCR5) for Rantes, MIP-1β, and MIP-1α," The Journal of Biological Chemistry, The American Society for Biochemistry and Molecular Biology, Inc., 1996, pages 17161-17166, Vol. 271, No. 29, Issue of July 19 th , USA. | | | | |
| , | | MURAI, MASAKO, et al., "Active participation of CCR5 ⁺ CD8 ⁺ T lymphocytes in the pathogenesis of liver injury in graft-versus-host disease," The Journal of Clinical Investigations, July 1999, pages 49-57, Vol. 104, No. 1. | | | | |
| | | BALASHOV, KONSTANTIN E., "CCR5* and CXCR3* T cells are Increased in multiple sclerosis and their ligands MIP-1α and IP-10 are expressed in demyelinating brain lesions," Proc. Natl. Acad. Sci., June 1999, pages 6873-6878, Vol. 90, USA. | | | | |
| | | BRADLEY, LINDA, et al., The Journal of Immunology, vol. 162(5), pp. 2511-2520, March 4, 1999 | | | | |

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